



# United States Patent and Trademark Office

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/080,917	02/22/2002	Patrick Cadet	09598-006001	7797
26191	7590 06/06/2005		EXAM	INER
	HARDSON P.C.		LANDSMAN	ROBERT S
PO BOX 1022 MINNEAPOL	2 LIS, MN 55440-1022		ART UNIT	PAPER NUMBER
	,		1647	

DATE MAILED: 06/06/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

This action is FINAL. 2b)   This action is non-final.  3)   Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213.  Isposition of Claims  4)   Claim(s) 1-7 and 9-32 is/are pending in the application.  4a) Of the above claim(s) 3.5,11,13 and 15-32 is/are withdrawn from consideration.  5)   Claim(s) 1,2,4,6,7,9,10,12 and 14 is/are rejected.  7)   Claim(s)   is/are objected to.  8)   Claim(s)   are subject to restriction and/or election requirement.  pplication Papers  9)   The specification is objected to by the Examiner.  10)   The drawing(s) filed on   is/are: a)   accepted or b)   objected to by the Examiner.  Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  11)   The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.  riority under 35 U.S.C. § 119  12)   Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  a)   All   b)   Some * c)   None of:  1.   Certified copies of the priority documents have been received.  2.   Certified copies of the priority documents have been received in Application No.    3.   Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  * See the attached detailed Office action for a list of the certified copies not received.			Applicat	ion No.	Applicant(s)
Robert Landsman   1647			10/080,9	917	CADET ET AL.
The MAILING DATE of this communication appears on the cover sheet with the correspondence address—reviot for Reply  A SHORTEMED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.  Besselsons of time may be available under the provisions of 3° CFR 1.35(a). In so event, however, may a reply be limitely filled.  The period for reply appendix down the the provision of 3° CFR 1.35(a). In so event, however, may a reply be limitely filled to the period for reply subject to a state of the period for reply with the statistic pression with a state of the period for reply subject to reply and the period for reply with the state of the communication. If you will not be set or extended parted for reply will, by stated, cause the application is become ABNICONED (38 U.S.C. § 133).  Agree that the subject term equation of the period for reply will, by stated, cause the application is become ABNICONED (38 U.S.C. § 133).  The state of the period parted term equation of the period parted for a state of the communication. The period parted term equation is FINAL.  20) This action is FINAL.  20) This action is FINAL.  21) This action is FINAL.  22) This action is FINAL.  23) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Exparte Quayle, 1935 C.D. 11, 453 O.G. 213.  18] Claim(s) 1.2 4 0.3 2.3 is/are pending in the application.  4a) Of the above claim(s) 3.51.113 and 15-32 is/are withdrawn from consideration.  5b) Claim(s) is/are ellowed.  6b) Claim(s) is/are ellowed.  6c) Claim(s) is/are ellowed.  6c) Claim(s) is/are ellowed.  6c) Claim(s) is/are ellowed.  6c) Claim(s) is/are objected to be the Examiner.  7c) The reversingly filled on is/are: a) accepted or b) objected to by the Examiner.  Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  Replacement drawing sheet(s) including the correction is required if the drawing(s)		Office Action Summary	Examine	 9r	Art Unit
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A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 2 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.  The Mailing DATE OF THIS COMMUNICATION.  The period for may be specified under the provisions of 3° CFR 1.33(a), in no event, however, may a reply be timely filed  The period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered limely.  If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered limely.  If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered limely.  If the period for reply specified above is less than thirty (30) days, a reply within the sealing date of this communication.  Failure to reply within the sector extended period for reply with, by statutory and will explain the become ABANDONED (55 U.S. § 133).  If the section is provided above the sector explaints of the communication, were firmly filed, may reduce any search of the communication.  The section is provided any section of the section of the communication, were firmly filed, may reduce any search of the communication.  The section is provided any section of the section of the communication, were firmly filed, may reduce any search of the communication.  The section is provided any section of the section of the section is non-final.  This action is FINAL.  A) Claim (s) 1.2 4.6 and 9-32 is/are pending in the application.  4) Claim (s) 1.2 and 9-32 is/are pending in the application.  5) Claim (s) 1.2 and 9-32 is/are pending in the application.  5) Claim (s) 1.2 and 9-32 is/are pending in the application.  5) Claim (s) 1.2 and 9-32 is/are pending in the application.  5) Claim (s) 1.2 and 9-32 is/are pending in the application.  6) Claim (s) 1.2 and 9-32 is/are pending in the application.  6) Claim (s) 1.2 and 9-32 is/are pending in the application.  6) Claim (s) 1.2 and 9-	<del></del>	The MAILING DATE of this communication a			1
THE MALLING DATE OF THIS COMMUNICATION.  Extensions of time may be available under the provisions of 3°CFR 1.78(q). In no event, however, may a righty be timely filed after SSX (g) MORTHS from the maining date of this communication.  A provision of the provision of the communication of 3°CFR 1.78(q). In no event, however, may a righty be timely filed after SSX (g) MORTHS from the maining date of this communication. Provision of the communication of the communication.  Failure to reply within the set or extended period for reply well, by statute, cause the application to become ABANDONED (35 U.S.C. § 130). Any reply received by the Office later than three nonsiders after the mailing date of this communication, even if timely filed, may reduce any extend patent term adjustment. See 3°CFR 1.79(q).  Italia  1) Responsive to communication(s) filed on 20 April 2005.  2a) This action is FINAL.  2b) This action is non-final.  3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213.  Itsposition of Claims  4) Claim(s) 1-7 and 9-32 is/are pending in the application.  4a) Of the above claim(s) 3.5,11,13 and 15-32 is/are withdrawn from consideration.  5) Claim(s) 1,2,4,6,7,9,10,12 and 14, is/are rejected.  7) Claim(s) is/are allowed.  8) Claim(s) 1,2,4,6,7,9,10,12 and 14, is/are rejected.  7) Claim(s) are subject to restriction and/or election requirement.  pplication Papers  9) The specification is objected to by the Examiner.  10) The drawing(s) filed on is/are: a) accepted or b) objected to by the Examiner.  Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  11) Acknowledgment is made of a claim for	Period fo	or Reply			
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## **DETAILED ACTION**

#### 1. Formal Matters

- A. The Amendment dated 4/20/05 has been entered into the specification.
- B. Claims 1-32 were pending. Claim 8 has been canceled. Claims 3, 5, 11, 13 and 15-32 are withdrawn as being drawn to a non-elected invention. Therefore, claims 1, 2, 4, 6, 7, 9, 10, 12 and 14 are the subject of this Office Action.
- C. All Statutes under 35 USC not found in this Office Action can be found, cited in full, in a previous Office Action.

## 2. Claim Rejections - 35 USC § 112, first paragraph - scope of enablement

A. Claims 1, 2, 4, 6, 7, 9, 10, 12 and 14 remain rejected under 35 USC 112, first paragraph, for the reasons already of record on pages 3-4 of the Office Action mailed 12/16/04. Applicants argue that it is clear from the specification that mu3 is a splice variant of mu1 and mu2 receptors and that other mu3 receptors can be obtained using PCR based on mu1 and mu2 sequences. Applicants further argue that a receptor is considered a mu3 receptor if it has higher affinity for DAMGO than for morphine.

These arguments have been considered, but are not deemed persuasive. While it is disclosed in the specification that mu3 is a splice variant of mu1/mu2, there is no requirement for this in the claims. The claims are broader than the disclosure since the only limitation is that the receptor has higher affinity for DAMGO than for morphine. While this limitation was added to claim 1 as per the Examiner's suggestion, the claims are still of excessive breadth. Claim 1 encompasses any mu3 receptor from any species whereas Applicants have only disclosed a mu3 receptor of SEQ ID NO:4, a human receptor, having the variation seen in SEQ ID NO:1. The specification does not teach other splice variants of mu3 in humans, nor of mu3 receptors from other species, nor is there anything in the claims which require that the mu3 receptor is a splice variant of mu1 or mu2.

This is further problematic given, for example, claim 2, which provides coordinates identifying various lengths and percent identity for the region corresponding to SEQ ID NO:1. As written, claim 1 is excessive since there is no recitation of the receptor having mu1 or mu2 sequences. Therefore, any receptor which has an increased affinity for DAMGO relative to morphine would be covered by the claims, regardless of whether or not is a splice variant of mu1/mu2 or structurally distinct. Given this, the

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only structural requirement in claim 2 are for the residues of SEQ ID NO:1 which is only a small portion of the entire receptor. Since the claim recites that the variant only has to be 65% identical to 15 bases of SEQ ID NO:1 (5 amino acids), which is 9-10 amino acids, this breadth is also excessive. In this embodiment, Applicants have only clearly defined 5 of 314 residues of the protein. There are no teachings in the specification which residues are required for protein function. Though it may be arguable that mu1 and mu2 receptors are well-known, Applicants have still not identified the residues critical for mu3 activity. Therefore, claiming that only 5 of 26 residues must be retained for function warrants undue experimentation, unless Applicants can provide evidence that it was well-known at the time of the invention which residues are required for mu3 receptor activity.

Regarding claims to hybridization, the same issues would apply. However, there is no structural requirement for these encoded proteins. All that is required is hybridization.

# 3. Claim Rejections - 35 USC § 112, first paragraph - written description

A. Claims 1, 2, 4, 6, 7, 9, 10, 12 and 14 remain rejected under 35 USC 112, first paragraph, for the reasons already of record on page 4 of the Office Action mailed 12/16/04. Applicants argue that it is clear from the specification that mu3 is a splice variant of mu1 and mu2 wherein a specific sequence of mu1/mu2 has been replaced with other amino acids. Applicants further argue that common molecular cloning techniques can be used to identify other variants.

These arguments have been considered, but are not deemed persuasive for the reasons discussed above in the scope of enablement rejection. Applicants have only adequately described one species of mu3 receptor, that of SEQ ID NO:4. No other species are described, or structurally contemplated, within the instant specification. Therefore, one skilled in the art cannot reasonably visualize or predict critical nucleic acid residues which would structurally characterize the genus of nucleic acids encoding the genus of mu3 proteins claimed, because it is unknown and not described what structurally constitutes any different nucleic acids encoding mu3 receptors, or nucleic acids encoding mu3 receptors from any different species, which are further not described; thereby not meeting the written description requirement under 35 USC 112, first paragraph.

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4. Claim Rejections - 35 USC § 112, first paragraph - new matter

Claims 7 and 8 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the

written description requirement. The claim(s) contains subject matter which was not described in the

specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s),

at the time the application was filed, had possession of the claimed invention. The claims recite

"consisting essentially of." Support for this limitation cannot be found in the specification. Furthermore,

if no verbatim support is found, the phrase will be interpreted as "comprising."

5. Claim Rejections - 35 USC § 112, second paragraph

A. All rejections under 35 USC 112, second paragraph, have been withdrawn in view of Applicants'

amendments to the claims.

6. Claim Rejections - 35 USC § 102

A. The rejection of claims 6 and 7 under 35 USC 102 has been withdrawn in view of Applicants'

arguments that Birren do not teach an "isolated" nucleic acid, nor one which preferentially binds

DAMGO to morphine.

B. The rejection of claim 9 under 35 USC 102 has been withdrawn in view of Applicants'

amendment to the claim. Fimiani do not teach a recombinant cell.

7. Conclusion

A. No claim is allowable.

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Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

#### Advisory information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert Landsman whose telephone number is (571) 272-0888. The examiner can normally be reached on M-Th 10 AM - 7 PM (eastern); alt F 10 AM - 6 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on 571-272-0961. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Robert Landsman Primary Examiner Art Unit 1647

PRIMARY EXAMINER